DEC 2 1 2005

K052780

>>Summary of Safety & Effectiveness

510(k) Summary as required by section 807.92(c)

Date: 03 16/05

Submission Applicant:
Bredent - Products for the
dental technician laboratory
Weissennornerstr. 2
89250 Senden

Phone: xx49-7309-872-230
Fax: xx49-7309-872-24
E-mail: info@bredent.com

Establishment Registration Number:
1000303432

Application corresondent/Contact person:
think - healthcare management
Schwarzwaldstr. 11
D-78532 Tuttlingen/Germany

Phone: xx49-7462-91300
Fax: xx49-7462-91301
E-mail: denk@denkgruppe.de

Trade name:
Bredent - Dentaplast

Common name:
Denture Relining, Repair/Rebasing resin

Classfication name:
Denture Relining, Repair/Rebasing resin, Dental (21 CFR 872.3760 - EBI)

Substantial Equivalence Claim:
K831647 - Dentsply -

Description of the Device:
Dentaplast hot is a polymerizing denture resin on the basis of methylmetacrylate. Dentaplast hot allows to obtain extended processing time and offers fine flowability and is therefore matched with the Dentaplast hot casting sstem. The catalyst is free from tertiary amine and ensures high colour stability. Dentaplast is entirely cadmium-free.
Application range:
-Fabrication of full dentures in the resin casting technique
-Completion of CoCr dentures
-Relinings and shaping of functional margins
-any type of repair work such as cracks, fractures.

>>Summary of Safety & Effectiveness

Indications for Use:
The bredent denture relining, repairing or rebasing resin is intended to reline a denture surface that contacts tissue, to repair a fractured denture, or to form a new denture base.

Comparison with P.D.

The Bredent product is similiar to the P.D. in terms of technical characteristics, design, Indications for Use, Target population, where it is used, performance, biocompatibility characteristics as well as sizes and configurations. Therefore the Bredent product can be deemed substantially equivalent and safe and effective for its indicated use.

Summary

The presented data that was conducted on the Bredent products shows in its results and in comparison to the predicate devices that the products are absolutely safe and effective for their intended use and do not raise any questions regarding safety and effectiveness. All models that are covered by this 510(k) premarket notification have been on the market in Europe for many years with no device failures. The used materials are well researched and do not raise any kind of question regarding safety and effectiveness of the finished product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 1 2005

Bredent
C/O Mr. Markus Denk
Think – Healthcare Management
Schwarzwaldstr. 11
D-78532 Tuttlingen
GERMANY

Re: K052780
Trade/Device Name: Dentaplast
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, or Rebasing Resin
Regulatory Class: II
Product Code: EBI
Dated: November 09, 2005
Received: November 16, 2005

Dear Mr. Denk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu S. Lin, PhD
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052780

Device Name: Dentaplast

Indications For Use: The bredent denture relining, repairing or rebasing resin is intended to reline a denture surface that contacts tissue, to repair a fractured denture, or to form a new denture base.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

Division of General Hospital
Dental, Infection Control, and General Devices

K052780